PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	STEVEN E. WALAK	Confirmation No.:	3380
Serial No.:	10/725,890	Examiner:	Bradley J. Osinski
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Docket No.:	1001.1632101	Customer No.:	28075
Title:	COMPOSITE MEDICAL DEVICE AND METHOD OF FORMING		

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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	Date

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on June 18, 2008, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed August 7, 2008. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $510.00 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Steven E. Walak, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 015182, Frame 0291. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-22, 25-70 and 73-75 are pending in the application, of which, claims 28-56 are withdrawn. Claims 23-24 and 71-72 have been canceled from the application.

Claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter "Ren"), in view of *Viera*, U.S. Patent 6,039,699.

Claims 12, 17, 60 and 65 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Vera as applied to claims 1 and 57 above, and further in view of O'Brien et al., WO99/58184.

Claims 14 and 52 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al., US 6,306,105 (hereinafter "Rooney").

Claims 74 and 75 stand allowed.

Claims 1-22, 25-27, and 56-70 and 73 of the application are currently being appealed

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to medical devices, such as catheters and the like, that include a composite shaft or other such structure. In some embodiments, the composite elongated shaft can be constructed by forming the metallic outer portion including the first metallic material about a metallic inner portion including the second metallic material different from the first meet. The second metallic material can be more flexible than the first metallic material. See abstract.

Turning now to independent claim 1, which is directed to a composite medical device (figure 1, reference numeral 110) produced by a process comprising: constructing a composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) by forming (page 8, lines 23-29) a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material about a metallic inner portion (id. at reference numeral 112) including a lumen therein (figure 2, reference numeral 119; page 8, lines 14-16), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); and removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion (page 9, lines 4-8).

Claim 2 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing the segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) from the composite shaft to expose the segment of the metallic inner portion (id. at reference numeral 112) includes

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting. For simplicity and because the application was restricted to the embodiment of Figures 2 and 3, the references to the specification and drawings are primarily directed towards Figures 2 and 3 and the corresponding description in the specification, but this is not meant to be limiting as support may be found throughout the specification and in many of the Figures.

removing the segment of the metallic outer portion from the composite shaft in the distal region (figure 3, reference numeral 116; page 9, lines 19-21) of the composite elongate shaft (figure 3; page 9, lines 19-21).

Claim 3 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), also including allowing a second segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) of the composite shaft to remain disposed about a second segment of the inner portion (id. at reference numeral 112) of the composite shaft (figure 3, page 9, lines 23-25).

Claim 4 recites the composite medical device of claim 3 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion of the composite shaft includes allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion in the proximal region of the composite elongate shaft (figure 3; page 9, lines 23-25).

Claim 5 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the segment of the metallic outer portion figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) removed from the distal region of the shaft to expose the segment of the metallic inner portion(id. at reference numeral 112), and also including allowing a second segment of the metallic outer portion of the composite shaft to remain disposed about a second segment of the inner portion at the distal region of the shaft (page 10, lines 1-11).

Claim 6 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein constructing the composite elongate shaft comprises co-drawing the metallic inner portion with the metallic outer portion to form the composite shaft (page 8, lines 23-27).

Claim 7 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein constructing the composite elongate shaft comprises co-extruding the metallic inner portion with the metallic outer portion to form the composite shaft(page 8, lines 23-27).

Claim 8 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion

(figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) includes providing a tapered transition (figure 3, reference numeral 137) between a region in which the metallic outer portion is intact and a region in which the metallic outer portion has been removed (Figure3, page 12, lines 4-12).

Claim 9 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprises grinding a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion(figures 2-6, reference numeral 112; page 4, lines 26-27; page 5, lines 14-17; page 11, lines 21-25).

Claim 10 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion comprises etching a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion (page 11, lines 4-5).

Claim 11 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a nickel-titanium alloy (page 5, lines 14-19).

Claim 12 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises beta titanium (claim as originally filed).

Claim 13 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy (page 5, lines 14-20).

Claim 14 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy (page 5, lines 14-20).

Claim 15 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a hollow tube having a length, and the lumen extends along the entire length (Figure 2, reference numeral 119, page 4, lines 28-30; page 8, lines 12-13).

Claim 16 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal (page 5, lines 14-20).

Claim 17 recites the composite medical device of claim 12 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal (page 5, lines 14-20).

Claim 18 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a catheter (page 4, lines 16-19; Figure 1).

Claim 19 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a guide catheter (claim as originally filed).

Claim 20 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion comprises grinding a segment of the metallic outer portion from a segment of the metallic inner portion (page 11, lines 21-25), and the process further includes grinding a segment of the metallic inner portion to form a reduced outer diameter region on the metallic inner portion (id.; page 12, lines 14-16).

Claim 21 recites the composite medical device of claim 20 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the reduced diameter region of the metallic inner portion comprises a tapered portion (page 11, lines 18-19).

Claim 22 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing the segment of the metallic outer portion includes selectively removing part of the first metallic material to form a pattern of the first metallic material that remains on the shaft (page 10, lines 9-20).

Claim 25 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a hypo-tube catheter, a drug delivery catheter, a therapeutic catheter, a diagnostic catheter or a guide catheter (claim as originally filed.

Claim 26 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion (page 7, lines 7-9, 13-16).

Claim 27 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the outer portion has higher tortional rigidity than the metallic material of the inner portion (page 7, lines 7-22).

Claim 57 recites a composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprising a composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) including a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material formed about a metallic inner portion (id. at reference numeral 112) including a lumen defined therein (figure 2, reference numeral 119; page 8, lines 14-16), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); and the distal region of the shaft has a segment of the metallic outer portion removed from the composite shaft to expose a segment of the metallic inner portion (page 9, lines 4-8), wherein the distal region of the shaft is more flexible than the proximal region of the shaft (page 9, lines 19-25).

Claim 58 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) is a co-drawn or co-extruded shaft (page 8, lines 23-27).

Claim 59 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a nickel-titanium alloy (page 5, lines 14-19).

Claim 60 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises beta titanium (claim as originally filed).

Claim 61 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy (page 5, lines 14-21).

Claim 62 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy (page 5, lines 14-21).

Claim 63 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a hollow tube having a length, the lumen extending along the entire length (Figure 2, reference numeral 119, page 4, lines 28-30; page 8, lines 12-13).

Claim 64 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal (page 5, lines 14-26).

Claim 65 recites the composite medical device of claim 60 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten or refractory metal (page 5, lines 14-26).

Claim 66 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprises a catheter (page 4, lines 16-19; Figure 1).

Claim 67 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a guide catheter (claim as originally filed).

Claim 68 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion (page 7, lines 7-9, 13-16).

Claim 69 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the outer portion has higher torsional rigidity than the metallic material of the inner portion (page 7, lines 7-22).

Claim 70 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the distal region of the shaft having the segment of the metallic outer portion removed from the composite shaft also includes a second segment of the metallic outer portion that remains on the composite shaft in a pattern (page 10, lines 9-20).

Claim 73 recites a composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprising a composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) including a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material formed (page 8, lines 23-29) about a metallic inner portion (id. at reference numeral 112) including a lumen defined therein (figure 2, reference numeral 119; page 8, lines 14-16), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); means for providing the distal region with a higher level of flexibility relative to the proximal region (page 9, lines 4-8); and means for providing the proximal region with a higher level of stiffness relative to the distal region (page 9, lines 4-8).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 are unpatentable under 35 USC 103(a) over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter "Ren"), in view of *Viera*, U.S. Patent 6,039,699?

2. Whether claims 12, 17, 60 and 65 are unpatentable under 35 USC 103(a) over Ren and Vera as applied to claims 1 and 57 above, and further in view of O'Brien et al., WO99/58184?

3. Whether claims 14 and 52 are unpatentable under 35 USC 103(a) over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al., US 6,306,105?

VII. ARGUMENT

A. CLAIMS 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68 AND 73 ARE PATENTABLE OVER REN ET AL., U.S. PATENT NO. 6,045,547, IN VIEW OF VIERA, U.S. PATENT NO. 6,039,699, UNDER 35 U.S.C. § 103(a).

1. All claim limitations must be considered.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Claim 1, for example, recites "constructing a composite elongate shaft by forming a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein." As described in the specification on page 8, line 27, "such unitary construction allows the formation of a composite shaft 110 that can be co-drawn and straightened such that the inner portion 112 and the outer portion 114 are formed together as one unitary construction." The structure of this claim element, therefore, is disclosed by neither Ren nor Viera.

Ren is directed towards catheters made of polymer layers, with the possible inclusion of a wire braid or helix as a stiffening member. Viera is directed to a solid metallic core wire that may have a metallic sleeve disposed thereon. Significantly, this sleeve is formed separately and then secured to the core wire by an adhesive, welding, brazing or soldering. Viera, col. 4, ll. 26-29.

The mere substitution of the metallic materials of Ren, with the joining methods taught by Ren of adhesive, welding, brazing or soldering, would not produce the claimed structure. In contrast, constructing a shaft by forming the metallic outer portion about a metallic inner portion creates a composite shaft of unitary construction. See the specification at page 8, lines 23-29. In essence there is a metallic bond between the two layers running the length of the shaft. This

metallic composite shaft of two distinct layers is a structural element that is not disclosed in either reference.

"The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." MPEP 2113 citing *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). In the present case, there is a structural element of the claims not taught by the prior art, and the Examiner fails to show why this structural difference is a non-obvious difference over the cited art.

In the advisory action, the Examiner points to the polymer extruding process of Ren to attempt to correct this deficit. The Examiner argues that "one of ordinary skill in the art looking to apply the co-extrusion method of Ren to medals would appreciate the difference and would still be able to successfully create the invention as claimed and that any structural difference would be nonexistent."

In appellants view, this argument constitutes impermissible hindsight. One would look to the coextrusion method of Ren, which is described entirely in terms of polymers, to create a metallic composite medical device as claimed only in view of appellants disclosure and claims. Yet, as described in MPEP 2142, knowledge of appellants disclosure must be put aside in reaching the determination of obviousness. The legal conclusions must be reached on the basis of facts gleaned from the prior art.

If one were looking only at the disclosures of Ren and Viera, and if one were looking to make the catheter of Ren out of metals as taught by Viera, one would look to the metal fastening techniques as taught by Viera rather than the polymer techniques of Ren to create the catheter. One of skill in the art recognizes that working with polymers is substantially different than working with metal.

Polymeric extrusion and metallic extrusion are two distinct techniques that use different tooling, operate at significantly different temperatures and pressures, and have different applications. For example, in metal extrusion, it is not known to produce a smoothly tapered end transition such as shown with element 31 of Figure 3 of Ren. Appellants understand that wetting effects and the viscosity of the molten metal make such a tapered transition effectively

impossible. One may vary the thickness of extruded metal layers but appellants do not believe that such a long smooth taper to nothing as shown in Ren is practically possible with metal extrusion.

Viera teaches standard metal fastening techniques such as welding brazing or soldering, and appellants see no reason why one of skill in the art would select a polymer forming technique described by Ren over these common metal fastening techniques, without the use of impermissible hindsight.

As an analogy, consider a building made of bricks. Mortar is the preferred and perhaps very nearly the exclusive fastening means for building such a structure. It would nevertheless be obvious to make the same structure out of wood. When changing the material, one would not retain the mortar; one would switch to a fastening method more suiting to wood such as nails, screw or glue. To argue that one of ordinary skill in the art would even look to the co-extrusion means of Ren when making the catheter out of metal is impermissible hindsight.

Independent claim 57 recites "a composite elongate shaft including the metallic outer portion comprising a first metallic material formed about a metallic inner portion including a lumen defined therein" and Independent claim 73 recites "a composite elongate shaft including a metallic outer portion comprising a first metallic material formed about a metallic inner portion including a lumen defined therein." Because these claims contain essentially the same limitation as that discussed with respect to claim 1 above, appellants believe these claims, and those that depend therefrom, are allowable for the reasons discussed above.

Because, when all claim limitations are properly considered, Viera and Ren and do not suggest the desirability of the claimed invention, the Examiner has failed to establish a *prima facie* case of obviousness. As such, claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 are believed to be allowable over Ren in view of Viera.

B. CLAIMS 11, 17, 60 AND 65 ARE PATENTABLE OVER REN AND VIERA AS APPLIED AGAINST CLAIMS 1 AND 57, FURTHER IN VIEW OF O'BRIEN ET AL., WO99/58184, UNDER 35 U.S.C. § 103(a).

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Because these claims depend from one of claims 1 or 57 and contain additional elements, appellants

believe these claims to be allowable for at least that reason. The addition of O'Brien et al. to the prior art under consideration does not remedy the defects discussed above.

C. CLAIMS 14 AND 52 ARE PATENTABLE OVER REN AND VIERA AS APPLIED AGAINST CLAIMS 1 AND 57, FURTHER IN VIEW OF ROONEY ET AL., U.S. PATENT NO. 6,306,105, UNDER 35 U.S.C. § 103(a).

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Because these claims depend from one of claims 1 or 57 and contain additional elements, appellants believe these claims to be allowable for at least that reason. The addition of Rooney et al. to the prior art under consideration does not remedy the defects discussed above.

D. CONCLUSION.

For the reasons stated above, claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 are patentable over Ren et al. in view of Viera, claims 12, 17, 60 and 65 are patentable over Ren and Vera as applied to claims 1 and 57 and further in view of O'Brien et al., and claims 14 and 52 are patentable over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al. The rejection should therefore be overruled.

Respectfully submitted,

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By his Attorney,

Date: September 5, 2008

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VIII. CLAIMS APPENDIX

1. A composite medical device produced by a process comprising:

constructing a composite elongate shaft by forming a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region; and

removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

2. The composite medical device of claim 1, wherein removing the segment of the metallic outer portion from the composite shaft to expose the segment of the metallic inner portion includes removing the segment of the metallic outer portion from the composite shaft in the distal region of the composite elongate shaft.

3. The composite medical device of claim 1, also including allowing a second segment of the metallic outer portion of the composite shaft to remain disposed about a second segment of the inner portion of the composite shaft.

4. The composite medical device of claim 3, wherein allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion of the composite shaft includes allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion in the proximal region of the composite elongate shaft.

5. The composite medical device of claim 1, wherein the segment of the metallic outer portion removed from the distal region of the shaft to expose the segment of the metallic inner portion, and also including allowing a second segment of the metallic outer portion of the composite shaft to remain disposed about a second segment of the inner portion at the distal region of the shaft.

6. The composite medical device of claim 1, wherein constructing the composite elongate shaft comprises co-drawing the metallic inner portion with the metallic outer portion to form the composite shaft.

7. The composite medical device of claim 1, wherein constructing the composite elongate shaft comprises co-extruding the metallic inner portion with the metallic outer portion to form the composite shaft.

8. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion includes providing a tapered transition between a region in which the metallic outer portion is intact and a region in which the metallic outer portion has been removed.

9. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion comprises grinding a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

10. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion comprises etching a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

11. The composite medical device of claim 1, wherein the metallic inner portion comprises a nickel-titanium alloy.

12. The composite medical device of claim 1, wherein the metallic inner portion comprises beta titanium.

13. The composite medical device of claim 1, wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy.

14. The composite medical device of claim 1, wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy.

15. The composite medical device of claim 1, wherein the metallic inner portion comprises a hollow tube having a length, and the lumen extends along the entire length.

16. The composite medical device of claim 1, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal.

17. The composite medical device of claim 12, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal.

18. The composite medical device of claim 1, wherein the composite medical device comprises a catheter.

19. The composite medical device of claim 1, wherein the composite medical device comprises a guide catheter.

20. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion comprises grinding a segment of the metallic outer portion from a segment of the metallic inner portion, and the process further includes grinding a segment of the metallic inner portion to form a reduced outer diameter region on the metallic inner portion.

21. The composite medical device of claim 20, wherein the reduced diameter region of the metallic inner portion comprises a tapered portion.

22. The composite medical device of claim 1, wherein removing the segment of the metallic outer portion includes selectively removing part of the first metallic material to form a pattern of the first metallic material that remains on the shaft.

25. The composite medical device of claim 1, wherein the composite medical device comprises a hypo-tube catheter, a drug delivery catheter, a therapeutic catheter, a diagnostic catheter or a guide catheter.

26. The composite medical device of claim 1, wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion.

27. The composite medical device of claim 1, wherein the metallic material of the outer portion has higher tortional rigidity than the metallic material of the inner portion.

57. A composite medical device comprising:

a composite elongate shaft including a metallic outer portion comprising a first metallic material formed about a metallic inner portion including a lumen defined therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region; and

the distal region of the shaft has a segment of the metallic outer portion removed from the composite shaft to expose a segment of the metallic inner portion, wherein the distal region of the shaft is more flexible than the proximal region of the shaft.

58. The composite medical device of claim 57, wherein the composite elongate shaft is a co-drawn or co-extruded shaft.

59. The composite medical device of claim 57, wherein the metallic inner portion comprises a nickel-titanium alloy.

60. The composite medical device of claim 57, wherein the metallic inner portion comprises beta titanium.

61. The composite medical device of claim 57, wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy.

62. The composite medical device of claim 57, wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy.

63. The composite medical device of claim 57, wherein the metallic inner portion comprises a hollow tube having a length, the lumen extending along the entire length.

64. The composite medical device of claim 57, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal.

65. The composite medical device of claim 60, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten or refractory metal.

66. The composite medical device of claim 57, wherein the composite medical device comprises a catheter.

67. The composite medical device of claim 57, wherein the composite medical device comprises a guide catheter.

68. The composite medical device of claim 57, wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion.

69. The composite medical device of claim 57, wherein the metallic material of the outer portion has higher torsional rigidity than the metallic material of the inner portion.

70. The composite medical device of claim 57, wherein the distal region of the shaft having the segment of the metallic outer portion removed from the composite shaft also includes a second segment of the metallic outer portion that remains on the composite shaft in a pattern.

73. A composite medical device comprising:

a composite elongate shaft including a metallic outer portion comprising a first metallic material formed about a metallic inner portion including a lumen defined therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region;

means for providing the distal region with a higher level of flexibility relative to the proximal region; and

means for providing the proximal region with a higher level of stiffness relative to the distal region.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None